



Rev. 04/01

PATENTS  
Docket No. NaPro-18

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Kmiec et al.

Application No.: 10/681,074 Confirmation No.: 7677

Filed : October 7, 2003

For : METHODS AND COMPOSITIONS FOR REDUCING  
SCREENING IN OLIGONUCLEOTIDE-DIRECTED  
NUCLEIC ACID SEQUENCE ALTERATION

Group Art Unit : 1645

Hon. Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR  
INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is an Information Disclosure Statement in the above-identified application. This Statement is submitted:

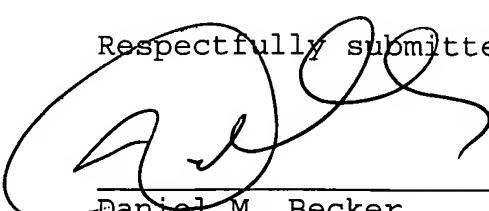
- within three months of the application filing date;
- more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in connection with this

Information Disclosure Statement to Deposit Account  
No. 06-1075. A duplicate copy of this letter is  
transmitted herewith.

Respectfully submitted,

19 FEB 2004

  
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Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98,  
applicants hereby make the following documents of record in  
the above identified application:\*

U.S. Patents and Patent Publications

6,573,046	06/03/03	Kmiec et al.
6,479,292	11/12/02	Metz et al.
6,303,376	10/16/01	Glazer
6,271,360	08/07/01	Metz
6,268,490	07/31/01	Imanishi et al.
6,136,601	10/24/00	Meyer
6,043,060	03/28/00	Imanishi
6,004,804	12/21/99	Kumar

\* Applicants reserve the right to challenge the status  
of any of the cited documents as prior art.

5,962,426	10/05/99	Glazer
5,955,363	09/21/99	Lewis
5,912,340	06/15/99	Kutyavin
5,888,983	03/30/99	Kmiec et al.
5,871,984	02/16/99	Kmiec
5,801,154	09/01/98	Baracchini
5,795,972	08/18/98	Kmiec
5,780,296	07/14/98	Holloman et al.
5,776,744	07/07/98	Glazer et al.
5,760,012	06/02/98	Kmiec et al.
5,756,325	05/26/98	Kmiec
5,731,181	03/24/98	Kmiec
5,565,350	10/15/96	Kmiec
5,422,251	06/06/95	Fresco
US 2003/0217377	11/20/03	Kmiec et al.
US 2003/0051270	03/13/03	Kmiec et al.
US 2002/0143952	10/03/02	Sugiarto et al.
US 2002/0119570	08/29/02	Yoon

Foreign Patents

WO 03/075856	09/18/03	PCT
WO 03/027640	04/03/03	PCT
WO 03/027265	04/03/03	PCT
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Other Documents

Alexeev et al., "Stable and inheritable changes in genotype and phenotype of albino melanocytes induced by an RNA-DNA oligonucleotide," *Nature Biotech.* 16:1343-1346 (1998)

Campbell et al., "Homologous recombination involving small single-stranded oligonucleotides in human cells," *New Biologist* 1:223-227 (1989)

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Crystal, Ronald G., "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," *Science* 270: 404-410 (1995)

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Kaji et al., "Gene and Stem Cell Therapies," *JAMA* 285(5) : 545-550 (2001)

Kmiec et al., "Targeted gene repair in mammalian cells using chimeric RNA/DNA oligonucleotides," *Cold Spring Harbor Monograph Series* 36: 643-670 (1999)

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Orrum et al., "Detection of the factor V Leiden mutation by direct allele-specific hybridization of PCR amplicons to photoimmobilized locked nucleic acids," *Clinical Chemistry* 45(11) : 1898-1905 (1999)

Parekh-Olmedo et al., "Targeted Neucleotide Exchange in *Saccharomyces cerevisiae* Directed by Short Oligonucleotides Containing Locked Nucleic Acids", *Chem. Biol.* 9:1073-1084 (2002)

Rando et al., "Rescue of dystrophin expression in *mdx* mouse muscle by RNA/DNA oligonucleotides," *Proc. Natl. Acad. Sci. USA* 97:5363-5368 (2000)

Rice et al., "The potential of nucleic acid repair in functional genomics," *Nature Biotech.* 19(4): 321-26 (2001)

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Tizzano et al., "Cystic fibrosis: Beyond the gene to therapy", *J. Pediat.* 120: 337-349 (1992)

Vasquez et al., "Chromosomal mutations induced by triplex-forming oligonucleotides in mammalian cells," *Nucl. Acids Res.* 27:1176-1181 (1999)

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Yamamoto et al., "Strand-specificity in the transformation of yeast with synthetic oligonucleotides," *Genetics* 131:811-819 (1992)

Yanez et al., "Therapeutic gene targeting," *Gene Therapy* 5:149-159 (1998)

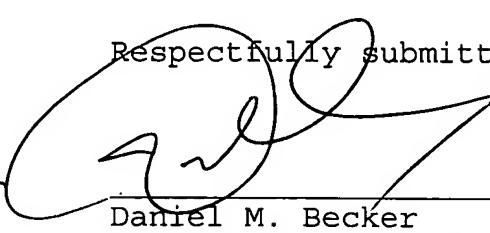
Yu et al., "An efficient recombination system for chromosome engineering in *Escherichia coli*", Proc. Natl. Acad. Sci USA 97:5978-5983 (2000)

Pursuant to the PTO's waiver of the requirement under 37 CFR 1.98 (a)(2)(i), 1276 OG 55, applicants have not submitted copies of each cited U.S. patent and each U.S. patent application publication. Copies of the aforementioned foreign patent publications and other documents, which are listed on the accompanying Form PTO-1449, are enclosed herewith.

It is respectfully requested that these documents be (1) fully considered by the Patent and Trademark Office during the examination of this application; and (2) printed on any patent that may issue on this application. Applicants request that a copy of Form PTO-1449, as considered and initialed by the Examiner, be returned with the next communication.

An early and favorable action is respectfully requested.

Respectfully submitted,

  
Daniel M. Becker  
Registration No. 38, 376  
Attorney for Applicants

I hereby Certify that this Correspondence is being Deposited with the U.S. Postal Service as First Class Mail in an Envelope Addressed to : HON.  
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P.O. BOX 1450, Alexandria,  
VA 22313-1450 on:

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Lorraine Coke

Name of Person Signing

Julie Cok

Signature of Person Signing

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1251 Avenue of the Americas  
New York, New York 10020-1104  
Tel.: (650) 617-4000

## 47U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,573,046	06/03/03	Kmiec et al.			
	6,479,292	11/12/02	Metz et al.			
	6,303,376	10/16/01	Glazer			
	6,271,360	08/07/01	Metz			
	6,268,490	07/31/01	Imanishi et al.			
	6,136,601	10/24/00	Meyer			
	6,043,060	03/28/00	Imanishi			
	6,004,804	12/21/99	Kumar			
	5,962,426	10/05/99	Glazer			
	5,955,363	09/21/99	Lewis			
	5,912,340	06/15/99	Kuttyavin			
	5,888,983	03/30/99	Kmiec et al.			
	5,871,984	02/16/99	Kmiec			
	5,801,154	09/01/98	Baracchini			
	5,795,972	08/18/98	Kmiec			
	5,780,296	07/14/98	Holloman et al.			
	5,776,744	07/07/98	Glazer et al.			
	5,760,012	06/02/98	Kmiec et al.			
	5,756,325	05/26/98	Kmiec			
	5,731,181	03/24/98	Kmiec			
	5,565,350	10/15/96	Kmiec			
	5,422,251	06/06/95	Fresco			
	US 2003/0217377	11/20/03	Kmiec et al.			
	US 2003/0051270	03/13/03	Kmiec et al.			
	US 2002/0143952	10/03/02	Sugiarto et al.			
	US 2002/0119570	08/29/02	Yoon			

EXAMINER

**DATE CONSIDERED**

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. NaPro-18	SERIAL NO. 10/681,074
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT Eric B. Kmiec et al.	
		FILING DATE October 7, 2003	GROUP 1645

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 03/075856	09/18/03	PCT				
	WO 03/027640	04/03/03	PCT				
	WO 03/027265	04/03/03	PCT				
	WO 03/027264	04/03/03	PCT				
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	WO 02/10364	02/07/02	PCT				
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	WO 01/73002	10/04/01	PCT				
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	WO 99/58702	11/18/99	PCT				
	WO 99/14226	03/25/99	PCT				
	WO 98/39352	09/11/98	PCT				X

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
	Alexeev et al., "Stable and inheritable changes in genotype and phenotype of albino melanocytes induced by an RNA-DNA oligonucleotide," <i>Nature Biotech.</i> 16:1343-1346 (1998)
	Campbell et al., "Homologous recombination involving small single-stranded oligonucleotides in human cells," <i>New Biologist</i> 1:223-227 (1989)
	Chan et al., "Targeted correction of an episomal gene in mammalian cells by a short DNA fragment tethered to a triplex-forming oligonucleotide," <i>J. Biol. Chem.</i> 274:11541-11548 (1999)
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	Verma et al., "Gene Therapy- Promises, Problems, and Prospects," <i>Nature</i> 389: 239-242 (1997)
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